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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 51570AWOM1XX24-P	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/DE99/00722	International filing date (day/month/year) 09 March 1999 (09.03.99)	Priority date (day/month/year) 10 March 1998 (10.03.98)
International Patent Classification (IPC) or national classification and IPC C12N 15/12		
Applicant METAGEN GESELLSCHAFT FÜR GENOMFORSCHUNG MBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 30 September 1999 (30.09.99)	Date of completion of this report 11 July 2000 (11.07.2000)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE99/00722

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☐ the international application as originally filed.

☒ the description, pages 1-103, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. 1-37, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig 1/10 - 10/10, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE99/00722

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 34-36, 1-37 (partially)

because:

- ☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 34-36, 1-37 (partially)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE 99/00722

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6, 11-15	YES
	Claims	7-10, 16-18, 32, 37	NO
Inventive step (IS)	Claims		YES
	Claims	1-33, 37	NO
Industrial applicability (IA)	Claims	1-28, 30-33, 37	YES
	Claims		NO

2. Citations and explanations

1. Since the international search report is restricted to the parts of Claims 1 to 33 and 37 which relate to SEQ ID Nos 3 and 67 to 70, the preliminary examination is carried out only for these subjects.

2. Attention is drawn to the following documents:

D1: "nj50f01.s1 NC1_CGAP_Pr9 Homo sapiens cDNA clone IMAGE: 995929". EMBL DATABASE ENTRY HS1321049; ACCESSION NUMBER AA531076 (VERSION 2), August 19, 1997, XP002127855

D2: HILLIER, L. ET AL.: "WashU-Merck EST project 1997: zw53c09.r1 Soares total fetus Nb2HF8 9w Homo sapiens cDNA clone 773776 5". EMBL DATABASE ENTRY HS1236638; ACCESSION NUMBER AA434549, June 1, 1997, XP002127856

D3: WO-A-98/04689 (UROCOR INC), February 5, 1998.

3. The application does not satisfy the requirements of PCT Article 33(2), because the subject matter of Claims 7 to 10, 16 to 18, 32, 34 and 37 is not

novel.

Documents D1 and D2 disclose partial sequences of the nucleic acid sequence SEQ ID No. 3 claimed in the present application and therefore anticipate the novelty of Claims 7 to 10, 32 and 37. The same applies to Claims 16 to 18, which relate to E. coli host cells.

4. Document D3, which is considered to be the closest prior art, discloses nucleic acid sequences which code for gene products overexpressed or underexpressed in prostate cancer tissue. The full sequence SEQ ID No. 3 claimed in the present application is not disclosed.

The problem to be solved can therefore be seen as being to isolate further human nucleic acids which are overexpressed or underexpressed in prostate cancer tissue.

Insofar as the solution proposed in Claim 1 of the present application relates to SEQ ID No. 3, it cannot be regarded as inventive (PCT Article 33(3)).

Document D3 describes the isolation of nucleic acid sequences which are overexpressed or underexpressed in prostate cancer tissue, using the differential display method. A person skilled in the art would consider it standard procedure to want to find further such nucleic acid sequences. Since the specific examples in the application do not demonstrate that the claimed sequence SEQ ID No. 3 fulfils a particular and/or surprising function, e.g. as an effective gene therapy agent, or that a

classic differential display method would not have led to this sequence, no inventive step can be acknowledged.

The same objection applies to Claims 2 to 33 and Claim 37.

5. Claim 29 relates to subject matter which, in this Authority's view, falls under PCT Rule 67.1(iv). No opinion with regard to industrial applicability is therefore established for the subject matter of these claims (Article 34(4)(a)(i)).